

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEDICIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

FOUGERA PHARMACEUTICALS INC.,
F/K/A NYCOMED U.S., INC.,

Defendant.

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§ CIVIL ACTION NO. 1:11-CV-04962-AJN

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§ JURY TRIAL REQUESTED

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**ANSWER AND DEFENSES OF DEFENDANT FOUGERA PHARMACEUTICALS INC.,
FORMERLY KNOWN AS NYCOMED U.S., INC.**

The defendant, Fougera Pharmaceuticals Inc. (“Fougera”), by its attorneys, hereby answers the numbered paragraphs of the Complaint of Plaintiff Medicis Pharmaceuticals Corporation (“Medicis”), for which every allegation not expressly admitted is denied, as follows:

FIRST DEFENSE

1. Medicis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is a leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and aesthetics conditions. Since its inception in 1988, Medicis has developed and commercialized numerous brand-name prescription medications in the therapeutic

categories Medicis serves. Because of their clinical effectiveness and high quality, Medicis' products have earned wide acceptance by both physicians and patients.

ANSWER:

Fougera admits that Medicis has a place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Fougera lacks knowledge or information to form a belief as to the truth or falsity of the allegations in this Paragraph 1, and therefore denies them.

2. Upon information and belief, Nycomed U.S. is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 60 Baylis Road, Melville, New York 11747.

ANSWER:

Fougera admits that it is a corporation organized and existing under the laws of the State of New York and has a place of business at 60 Baylis Road, Melville, New York 11747.

3. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*

ANSWER:

Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, Fougera admits that Medicis purports to assert a claim for patent infringement, but specifically denies that Medicis is entitled to any relief.

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Paragraph 4 contains legal conclusions to which no answer is required.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

ANSWER:

Paragraph 5 contains legal conclusions to which no answer is required.

6. This Court has personal jurisdiction over Nycomed U.S. by virtue of, virtue of its incorporation and place of business in New York. This Court also has jurisdiction over Nycomed U.S. by virtue of, *inter alia*, its transaction of business and derivation of substantial revenue from services or things used or consumed in this judicial district, its substantial and continuous contacts with this judicial district, and its purposeful availment of the rights and benefits of New York law. Upon information and belief, Nycomed U.S. engages in the manufacture, sale, and distribution of pharmaceutical products within the United States generally and the state of New York specifically.

ANSWER:

Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Fougera does not contest personal jurisdiction solely for purposes of this case. Otherwise denied.

7. Medicis incorporates by reference the averments set forth in paragraphs 1-6 as if fully set forth herein.

ANSWER:

Fougera restates and incorporates by reference its responses to Paragraph 1 to 6 as though fully set forth herein.

8. United States Patent No. 7,981,909 (“the ‘909 patent”), entitled “Use of 1-Hydroxy-2-Pyrodones for the Treatment of Seborrheic Dermatitis,” was duly and lawfully issued on July 19, 2011. A true and correct copy of the ‘909 patent is attached to this Complaint as Exhibit 1.

ANSWER:

Fougera lacks knowledge or information to form a belief as to the truth or falsity of the allegations in this Paragraph 8, and therefore denies them. Fougera expressly denies that the ‘909 patent “was duly and lawfully issued.” Fougera also expressly denies that a true and correct of the ‘909 patent is attached to the Complaint.

9. The ‘909 patent resulted from Application No. 13/018,417, filed on Jan. 31, 2011.

ANSWER:

Fougera admits that the face of the ‘909 patent recites Appl. No. 13/018,417, filed on Jan. 31, 2011. Otherwise denied.

10. Medicis is the owner of all rights, title, and interest in the ‘909 patent, including the right to sue and recover for infringement thereof.

ANSWER:

Fougera lacks knowledge or information to form a belief as to the truth or falsity of the allegations in this Paragraph 10, and therefore denies them.

11. The ‘909 patent recites four (4) claims directed to a “method of treating seborrheic dermatitis.” For example Claim 1 of the ‘909 patent recites:

A method of treating seborrheic dermatitis of the scalp comprising administering to the scalp of a human seborrheic dermatitis patient an

amount effective for the treatment of seborrheic dermatitis of a composition comprising only one active ingredient, the active ingredient consisting of ciclopirox, and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition and is a shampoo.

ANSWER:

Fougera admits that the '909 patent recites four claims directed to a "method of treating seborrheic dermatitis."

12. Medicis is the holder of New Drug Application No. 21-159 approved by the United States Food and Drug Administration for Loprox[®] Shampoo (ciclopirox) 1%. Loprox[®] Shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

ANSWER:

Fougera admits that public sources indicate that Medicis applied for New Drug Application No. 21-159 for LOPROX Shampoo (ciclopirox) 1% and that "Loprox Shampoo, 1%, is indicated for the treatment of seborrheic dermatitis on the scalp of adults." *See* http://findarticles.com/p/articles/mi_m0PDG/is_4_2/ai_106732280/. Otherwise denied.

13. On or about May 25, 2010, Nycomed U.S. received FDA approval for a generic ciclopirox 1% shampoo.

ANSWER:

Admitted.

14. Upon information and belief, Nycomed U.S.'s generic ciclopirox 1% shampoo is indicated for treating seborrheic dermatitis of the scalp.

ANSWER:

Fougera admits that the indications and usage section of its label reads that "Ciclopirox Shampoo 1% is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults." Otherwise denied.

15. Pursuant to federal regulation, including, without limitation, 21 C.F.R. Sections 314.94(a)(4) and (a)(8), Nycomed U.S.'s ANDA seeking approval of its generic ciclopirox 1% shampoo was required to contain a statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for its generic product had been previously approved for the reference listed drug, Loprox[®] Shampoo, and that its labeling is the same as the labeling of Loprox[®] Shampoo, except for certain differences not relevant here.

ANSWER:

Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Fougera denies the allegations of this paragraph.

16. Because Loprox[®] Shampoo is only indicated for the topical treatment of seborrheic dermatitis of the scalp in adults, upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), the label for Defendant Nycomed U.S.'s generic ciclopirox 1% shampoo contains the same indication and instructions for use as the label for Loprox[®] Shampoo.

ANSWER:

Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Fougera denies the allegations of this paragraph.

17. Upon information and belief, subject to Rule 11(b)(3), Nycomed U.S.'s generic ciclopirox 1% shampoo comprises the active ingredient ciclopirox and at least one surfactant and has a pH in the range of about 4.5 to about 6.5.

ANSWER:

Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Fougera denies the allegations of this paragraph.

18. The package insert for Nycomed U.S.'s generic ciclopirox 1% shampoo includes instructions for dosage and administration of the shampoo.

ANSWER:

Fougera admits that its package insert includes a "dosage and administration" section. Otherwise denied.

19. Upon information and belief, Nycomed U.S. has infringed, and is still infringing, the '909 patent, either directly and/or indirectly, literally or under the doctrine

of equivalents, by its activities, including making, using, offering for sale, selling in the United States or importing, without authority, ciclopirox 1% shampoo.

ANSWER:

Denied.

20. Nycomed U.S.'s infringing activities have caused and will continue to cause Medicis irreparable harm, for which it has no adequate remedy at law, unless Nycomed U.S.'s activities are enjoined.

ANSWER:

Denied.

21. Medicis has been and continues to be damaged by Nycomed U.S.'s infringement of the '909 patent in an amount to be determined at trial.

ANSWER:

Denied.

22. On or about June 4, 2011, Medicis notified Nycomed U.S. of the application that resulted in the '909 patent and provided a copy of the published application to Nycomed U.S.

ANSWER:

Fougera admits that by letter, dated June 3, 2011, it received from Medicis a copy of the published patent application US 2011/0112153 A1, corresponding to Application No. 13/018,417, which issued as the '909 patent. Otherwise denied.

23. Upon information and belief, Nycomed U.S.'s infringement of the '909 patent is willful and deliberate, and justifies an increase in damages of up to three times in accordance with 35 U.S.C. § 284.

ANSWER:

Denied.

24. Upon information and belief, Nycomed U.S.'s infringement of the '909 patent is exceptional and entitles Medicis to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

ANSWER:

Denied.

25. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Medicis demands a trial by jury of this action of all issues so triable.

ANSWER:

Fougera admits that Medicis purports to demand "a trial by jury of this action of all issues so triable."

Fougera further answers that any allegation in the Complaint requiring a response, and not specifically admitted, is denied.

SECOND DEFENSE

Fougera has not infringed, induced infringement, or contributed to infringement of the '909 patent.

THIRD DEFENSE

The '909 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code.

FOURTH DEFENSE

The Complaint fails to state a claim upon which relief may be granted.

FIFTH DEFENSE

The Court lacks subject matter jurisdiction because there is no claim or controversy, at least for Nycomed's activities prior to issuance of the '909 patent, and as to invalid or unenforceable patent claims.

SIXTH DEFENSE

The Complaint fails to state a claim for an exceptional case and/or a claim for willful infringement.

PRAYER FOR RELIEF

WHEREFORE, Fougera denies that Medicis is entitled to any of the relief requested, or to any relief at all, and respectfully requests that this Court:

- A. dismiss this action with prejudice;
- B. enter judgment in favor of Fougera;
- C. award Fougera its reasonable attorney's fees and the cost of defending this action pursuant to 35 U.S.C. § 285; and
- D. award Fougera such other further relief as the Court deems just and proper.

DEMAND FOR A JURY TRIAL

Fougera demands a jury trial on all claims so triable.

Dated: February 27, 2012

Respectfully submitted,

By: /s/ Peter J. Shen

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**ATTORNEYS FOR DEFENDANT
FOUGERA PHARMACEUTICALS INC.**

CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2012, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which will send notification of such filing to the following:

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/s/ Peter J. Shen

Peter J. Shen